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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,732	07/31/2001	Piero Anversa	674554-2002	6924

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/919,732	Applicant(s) ANVERSA, PIERO	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-153* is/are pending in the application.

4a) Of the above claim(s) *1-25,53-123 and 141-153* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-52 and 124-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-153 are pending in the present application.

Applicant's election with traverse the invention of Group II (claims 26-52 and 124-140) in Paper No. 9 is acknowledged. Applicants further elected with traverse the following species: (a) stem cell factor as a species of cytokine; and (b) myocytes as a species of differentiated cell type. Upon reconsideration, the species restriction for the differentiated cell type is withdrawn.

With respect to Group restriction, Applicants argue that the claims in Groups I, II and III are all classified in class 424, and that all of the claims involve methods for repairing and/or generating and/or regenerating myocardium and/or myocardial cells, and therefore the restriction requirement is inappropriate. Furthermore, there is no evidence that there would be undue or serious burden in examining all of the inventions. Applicants' arguments are respectfully found to be unpersuasive because the Inventions in Groups I-III are methods that have different method steps, starting materials and they can be practiced independently one from the others. The searches required for the presently claimed inventions are not limited only to class 424 of the patent database. For example each group requires a different non-patent literature database search (cytokine, stem cells, combinations of stem cells/different cytokines).

With respect to species restriction on a cytokine, Applicants argue that when a generic claim includes sufficiently few species that a search and examination of all the species at one time would not pose a serious burden on the examiner, and that the search and examination would be sufficiently co-extensive such that the cytokines

should be searched and examined as a whole. Therefore, the species restriction should be withdrawn. Applicants' arguments are respectfully found to be unpersuasive because a generic claim lists 8 distinct species, not a few species (e.g., 3-4), which are chemically and structurally distinct molecules, all of which are classified as a cytokine. A search and examination for all of the 8 distinct species would pose a serious burden on the examiner.

Accordingly, the restriction is made **FINAL**. Claims 1-25, 53-123 and 141-153 are withdrawn from further consideration because they are drawn to non-elected inventions.

Claims 26-52 and 124-140 are examined on the merits herein.

Priority

Upon reviewing the specification of the present application with the specifications of the provisional applications from which Applicants claim priority, claims 26-52 and 124-140 are at best entitled to the priority date of 12/29/2000 from the provisional application 60/258,564 which discloses the mobilization of hematopoeitic stem cells from the hematopoietic system through the administration of stem cell factor (SCF) and granulocyte-colony stimulating factor (G-CSF) that leads to regeneration of infracted myocardium in mice.

Claim Objections

Claim 46 is objected to because of the following informalities: the term "myocyctes" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-52 and 128-140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 26 and its dependent claims, it is unclear what is encompassed by the phrase "A method of repairing and/or generating and/or regenerating recently damaged myocardium". This is because it is unclear which aspect of the generation or regeneration of a recently damaged myocardium would or would not fall within the scope of repairing the recently damaged myocardium. The scopes of generating and regenerating and repairing processes are not defined in the present application. Therefore, the metes and bounds of the claims are not clearly determined. Furthermore, as written it is unclear whether Applicants claim a method of generating recently damaged myocardium and/or myocardial cells or a method of generating myocardial cells in a recently damaged myocardium and/or myocardial cells? Clarification is requested because the metes and bounds of the claims are not clearly determined.

Claim 33 recites the limitation "the patient" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of any patient in claims 26-28 from which claim 33 is dependent upon.

Claim 128 recites the limitation "the patient" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of any patient in claims 124, 126 from which claim 128 and its dependent claims are dependent upon.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-52 and 124-140 are rejected under 35 U.S.C. 102(b) as being anticipated by Isner et al. (WO 99/45775).

Claims 26-52 are drawn to a method of repairing and/or regenerating recently damaged myocardium and/or myocardial cells comprising the administration of a cytokine. Claims 124-140 are directed to a method of implanting or depositing cells or causing the implantation or deposition of somatic stem cells in cardiac or blood vessel tissue comprising administration of a cytokine.

Isner et al. disclose a method for forming new blood vessels or preventing or reducing the severity of blood vessel damage associated with ischemia or related

conditions in a mammal comprising administering to the mammal an effective amount of a vascularization agent such as Stem cell factor (SCF, also known as Steel factor), GM-CSF, VEGF and others (See Summary of the Invention, pages 4-12). Conditions that are conducive to damaging blood vessels include ischemic vascular diseases such as ischemic cardiomyopathy, myocardial ischemia, limb ischemia; and that ischemia may especially adversely impact heart or brain tissue as often occurs in cardiovascular disease or stroke, respectively (page 15, lines 1-10). The vascularization agent can be administered into a human patient in need of treatment through various routes including subcutaneous, intravenous, intraarterial, intramuscular and intraperitoneal (page 18, lines 14-19). Isner et al. further teach that the preferred *in vivo* dosages for the vascularization agents are from about 1μg/kg/day to about 100 μg/kg/day (page 19, lines 2-3).

Since the methods taught by Isner et al. have the same step (administration of SCF at an effective amount from about 1μg/kg/day to about 100 μg/kg/day) as the presently claimed methods, they also inherently stimulate or mobilize the treated patient's own somatic stem cells.

Accordingly, Isner et al. anticipate the instant claims.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Remy Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

PATENT EXAMINER
Gerald G. Leffers Jr
A.U. 1636